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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,297	09/21/2005	Raymond Andrieu	LEMAN.001APC	1931

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KNOBBE MARTENS OLSON & BEAR LLP
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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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12/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/550,297	Applicant(s) ANDRIEU ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/13/09, 9/1/09</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23, 28, and 31-35 are rejected under 35 U.S.C. 103(a) as being anticipated by Moe et al. (US Pub. No. 2003/0023302) in view of Verona et al. (US Pat. No. 7,323,010). Moe et al. discloses the following of the claimed invention: a biological prosthesis comprising an aortic valve (11; paragraphs 0004-0005); a tubular wall (12); and a reinforcement device (16) comprising a rod (13) implanted in the tubular outer wall. Claims 22, 23, 28, and 31-35 are disclosed as shown in Figures 1A and 1B.

Moe et al. does not teach obtaining an aortic valve from an animal. Verona et al. teaches a heart valve that uses a combination of synthetic materials to construct the body of the valve with materials obtained from an animal to construct the cusps of the valve in col. 5, line 59 through col. 6, line 42 for the purpose of utilizing both the strength of the synthetic materials and the compatibility of the animal materials. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moe et al. by using the valve materials described by Verona et al. in order to utilize the strength and compatibility of the Verona et al. materials.

Please note that because the term “comprising” was used in the claims, the claims allow for additional elements not specified in the claims to be present in the prior art. In the instant

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case, the synthetic materials of Verona et al.'s heart valve may be used in conjunction with the valve obtained from an animal described in the claims.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moe et al. in view of Verona et al., further in view of Rosen (US Pat. No. 4,345,340). Moe et al., as modified by Verona et al., teaches the invention substantially as claimed, however, they do not teach the use of commissure points. Rosen teaches a heart valve with commissure points in col. 3, lines 5-15 for the purpose of securing the tubular wall to the reinforcement device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Moe et al. by using commissure points to secure the tubular wall to the reinforcement device.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moe et al. in view of in view of Verona et al., further in view of Gupta (US Pat. No. 4,851,000). Moe et al., as modified by Verona et al., teaches the invention substantially as claimed, however, they do not teach coating the reinforcement device with a fluoropolymer material. Gupta teaches a heart valve with a fluoropolymer material coating on the reinforcement device in col. 4, lines 40-50 for the purpose of making the prosthesis more durable. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Moe et al. by using a fluoropolymer material coating on the reinforcement device in order to make the prosthesis more durable.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moe et al. in view of Verona et al., further in view of Pavcnik et al. (US Pub. No. 2001/0039450). Moe et al., as modified by Verona et al., teaches the invention substantially as claimed, however, they

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do not teach the intraparietal reinforcement devices having helical shapes. Pavcnik et al. teaches an implantable valve with an intraparietal reinforcement device that has a helical shape in Figures 2-8 and paragraphs 0008-0010 for the purpose of helping the prosthesis to better conform to the rounded contours of the vessel it is placed in. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Moe et al. by giving the intraparietal reinforcement devices helical shapes in order to help the prosthesis to better conform to the rounded contours of the vessel it is placed in.

Response to Arguments

Applicant's arguments filed 3/30/2009, with respect to the Angell et al. reference, have been fully considered but they moot on the grounds of the new rejection. Regarding the Moe et al. reference, the Applicant contends that the prior art's stents and tabs are not implanted into the valve body. The examiner respectfully disagrees. Based on the Figure 1A, it appears that valve consists of a single body, and the lines located near element "12" define its parameters. In addition, there is no language in the specification stating that the valve is made of two separate layers, or how those layers would be attached to each other and/or the valve periphery.

The Applicant further contends and implies in the Declaration of 12/29/2008 that Moe et al. teaches away from using natural valve tissues. While Moe et al. indicates that there may be disadvantages to using natural tissues, the prior art does not specifically states that natural tissues cannot be used, nor would the device of Moe et al. be destroyed with a natural tissue valve. In addition, the current secondary reference uses synthetic materials where the tabs would be implanted, and reserves the use of the animal tissue to the valves themselves. This will allow the

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materials to be strong enough to be used on the Moe et al. device, while still meeting the claims' limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774

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